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No. 95-728

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

WARNER-JENKINSON COMPANY, INC.
Petitioner,

v.

HILTON DAVIS CHEMICAL CO.
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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STATEMENT OF INTEREST

The Biotechnology Industry Organization ("BIO") files this *amicus curiae* brief in the appeal of *Hilton Davis Chemical Co. v. Warner-Jenkinson Company, Inc.*, 62 F.3d 1513 (Fed. Cir. 1995). Written consent to the filing of this brief has been obtained from the petitioner and the respondent and is being filed herewith.

The matter before the Court raises the most fundamental question about our patent system, the scope of protection to be accorded under a United States patent. The role that the doctrine of equivalents plays in determining that scope is of profound importance to BIO.

BIO represents over 580 companies, academic institutions, state biotechnology centers and related organiza-

tions in 47 states and more than 20 nations, engaged in the development of products and services in the areas of agriculture, biomedicine, biopharmaceuticals, diagnostics, food, energy and environmental applications. BIO's members conduct research and development programs primarily directed to the discovery of innovative techniques and products to treat and diagnose diseases and disorder. To date, the biotechnology industry has produced 39 drugs approved for commercialization by the Food & Drug Administration ("FDA"); these drugs have been used to treat over 60 million people. The diseases that these drugs treat include AIDS, cancer, diabetes, multiple sclerosis, cystic fibrosis and many other serious malodies. For most of these diseases, there were no known treatments prior to the development of the biotechnology product. BIO's members almost always seek to patent these inventions.

In 1995, our industry invested 7.7 billion dollars on research and development and production facilities. The biotechnology industry invested at nine times the rate of the average of other United States companies. This investment is particularly remarkable when it is realized that, because of their youth, only 5% of our industrial members earn a profit. The patent system and the doctrine of equivalents play a fundamental role, therefore, in determining the expected future value of inventions developed by our members.

A patent system that rewards innovation is essential for all innovators who seek protection for their discoveries. The biotechnology industry is a relatively nascent industry, with the number of beneficial new products in the research and development pipeline far outnumbering the actual products which have been placed in commerce. In our industry, a lead time of 10 years from initiation of product development to approval for commercialization by the FDA is typical. At this stage in the development of our emerging industry, patents represent a critically important and tangible benchmark which

investors look to for assurance that their investments in the exciting new products of the future will be adequately protected. Accordingly, *amicus* has an interest in ensuring that our Nation's patent system provides the complete range of protection necessary to fully protect the inventions developed by its members.

The issue before the Court transcends the biotechnology industry. The substantive doctrines of patent law must apply to all technologies in the same way; inventors from the biotechnology industry should be treated no less or no more favorably than inventors from other industries. However, inventors from our industry have a special interest in this issue because the incentives to invest in future research and development and the approach taken to apply for and prosecute claims to inventions from our industry will both be dramatically influenced by the Court's decision.

This brief will set forth the importance of the doctrine of equivalents to the biotechnology industry. This brief will not focus on other, albeit important, issues (e.g., whether the range and scope of equivalents is to be determined by the judge, the jury, or both). The comments and positions presented in this brief will, accordingly, be limited.

SUMMARY OF THE ARGUMENT

BIO submits this *amicus* brief to assist the Court in appreciating an important point in considering the role of the doctrine of equivalents: the doctrine of equivalents, as an aid to construing the scope of a patent to ensure that an innovator's *invention* is accorded the full protection intended under our Nation's patent laws and regulations. Under our patent system, an innovator who has met the statutory criteria for patentability as defined in 35 U.S.C. §§ 101, 102, 103 and 112, is entitled to exclude others from making, using, offering for sale, selling or importing the patented invention. As codified

in 35 U.S.C. § 271(a),[1] literal infringement is based upon the "patented invention." The legal parameters for determining whether there has been infringement must always be considered in the context of the patented invention.

From BIO's perspective, the most important issues raised by petitioner are an effort to have the Court abolish the doctrine of equivalent or limit its application to situations where the subjective intent of the accused infringer influence the outcome. Other issues are raised by the decision below and are, or will be, addressed by petitioner and respondent. The purpose of this brief, however, is to urge the Court to maintain the doctrine of equivalents and to ensure its application without regard to the intent of the alleged infringer.

If an accused device or process falls within the actual language of the claims, literal infringement is found.[2] In

[1] "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell or sells any patented invention, within the United States or imports into the United States any *patented invention* during the term of the patent therefore, infringes the patent." (emphasis added).

[2] According to the Court's recent decision in *Markman v. Westview Instruments, Inc.*, 64 U.S.L.W. 4263 (1996), the scope of a patent claim is a question of law to be determined by the Court.

Another important doctrine related to claim construction is the reverse doctrine of equivalents. This doctrine has been applied in limited circumstances to find no literal infringement where the literal scope of the claims is determined to be overly broad. In these situations, the reverse doctrine serves the same equitable purpose as the doctrine of equivalents by allowing the patented invention to be considered such that the form of the claim does not triumph over the substance of the patented invention. *See Scripps Clinic & Research Found. v. Genentech Inc.*, 833 F.2d 931, 962 (Fed. Cir. 1991); *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 927 F.2d 1565, 1561 (Fed. Cir. 1988); *Pennwalt Corp. v. Durand-Wayland Inc.*, 846 F.2d 1369, 1372 (Fed. Cir. 1987); and *In re Hogan*, 559 F.2d 595, 607 (C.C.P.A. 1977) ("Like the judicially-developed doctrine of equivalents, designed to protect the patentee with respect to later-developed variations of the claimed

certain circumstances, the invention as defined by the claims is not literally infringed, but the accused device, composition or process differs in an *insubstantial* way from the invention as literally claimed. An analysis of infringement under the doctrine of equivalents permits the patentee to obtain protection for the patented invention, including these minor or insubstantial variations from the claims. Many years of patent law jurisprudence have upheld the idea that equity requires that equivalents be considered as part of the claimed invention. Few patent doctrines are as ancient yet maintain such currency. Thus, this Court most recently recognized this in *Markman v. Westview Instruments, Inc.*, 64 U.S.L.W. 4263 (1996), where, citing Schwartz, *Patent Law and Practice* 1, 82 (2nd Ed. 1995), it noted that the claim of a patent "functions to forbid not only exact copies of an invention, but products that go to the heart of the invention but avoid the literal language of the claim by making a *non-critical* change." (emphasis added). No decision of any court has held that the doctrine of equivalents can be extended beyond noncritical, i.e., insubstantial, differences.

We believe that only through the application of the doctrine of equivalents can the patentee adequately protect the *substance* of the patented invention. To limit the patented invention to the literal language of the claims would permit another to appropriate the patented invention by making any one of an almost limitless number of small, insignificant or insubstantial changes to avoid the literal claim language. Moreover, abolishing the doctrine of equivalents would create an undue and unneces-

invention, the judicially-developed 'reverse doctrine of equivalents,' requiring interpretation of claims in light of the specification, may be safely relied upon to preclude *improper* enforcement against later developers."). As such, petitioner might be questioned as to how this Court can undercut or remove the doctrine of equivalents without also undercutting or removing the reverse doctrine of equivalents.

sary burden on the biotechnology patent applicant, the Patent & Trademark Office ("PTO") and the public at large. We shall describe one example of such a burden effecting our industry if the doctrine is abolished (see *infra* pages 7-10.

In order to balance the equities of the inventor's right to protect equivalents with the need to provide reasonably certain boundaries of patent protection, there are strict limitations placed upon the doctrine of equivalents. For example, the doctrine of equivalents is subordinate to limitations imposed by the prosecution history estoppel doctrine. The prosecution history estoppel doctrine precludes a patentee from recapturing subject matter that was given up during prosecution to obtain allowance. The doctrine of equivalents is also limited by the prior art. Equivalents cannot encompass that which formed part of the prior art.

Petitioner argues that the doctrine of equivalents is inconsistent with the legislative machinery for correcting patents by reissue. We shall show below that the doctrine of equivalents is distinct from and not inconsistent with the mechanism provided for in the reissue patent statute.

Although the doctrine of equivalents can be viewed as being equitable in nature, this only ensures that the patented invention is not violated under circumstances where literal infringement is avoided. Infringement under the doctrine of equivalents is infringement. There is no principle which recognizes "innocent" or "accidental" infringement. Petitioner, the alleged infringer, and several of the *amici*, urge in the alternative that if the Court is unwilling to abolish the doctrine, then it should be restricted, because of its "equitable" nature, to alleged infringers who have knowingly sought to steal the substance of the patented invention by exploiting a weakness in the claims. In other words, depending upon an alleged infringer's knowledge or lack of knowledge of a patent and a subjective determination of their intent, two individuals doing exactly the same thing would in one situation be found to infringe and in another held not to be liable. We believe that such a dichotomy is not only unfair to the innovator, but unworkable and subject to abuse.

ARGUMENT

I. FOR PATENTED INVENTIONS INVOLVING "SOPHISTICATED" TECHNOLOGIES, THE DOCTRINE OF EQUIVALENTS IS CRITICAL FOR ENSURING PROTECTION FOR THE PATENTED INVENTION

BIO urges this Court to maintain the doctrine of equivalents as a tool to be used in properly determining the scope and meaning of the claims.

Maintaining the doctrine of equivalents is particularly important to the biotechnology industry, given the nature of the technology which we utilize. The diversity of our industry prevents the illustration of the importance of the doctrine of equivalents to our members in a single example. However, to better understand and appreciate our position, we provide a brief illustration of a technological approach used by many of our members in harnessing the power of recent advances in molecular biology to the development of bio-pharmaceuticals.

Many biotechnology inventions relate to proteins. Insulin is an example of a well known protein. A variety of life-saving and life-enhancing therapeutic proteins have been developed by BIO members that have been approved for commercialization by the FDA; many other proteins are currently being investigated in human clinical trials; other proteins have been discovered and are being investigated in pre-clinical settings.

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[8] Alanine, Cysteine, Aspartic Acid, Glutamic Acid, Phenylalanine, Glycine, Histidine, Isoleucine, Leucine, Lysine, Methionine, Asparagine, Proline, Glutamine, Arginine, Serine, Threonine, Valine, Tryptophan, and Tyrosine.

A "protein" is a biological molecule defined by a specific arrangement of "amino acids." There are 20 naturally occurring amino acids.[3] A single amino acid is encoded by a specific grouping of three deoxyribonucleotide ("DNA") bases (also referred to as "nucleotides"), this grouping of three bases being referred to as a "codon." The arrangement of amino acids or DNA bases is referred to as a "sequence". There are four different DNA bases.[4] There are 64 possible codons (4^3), with 61 of these actually encoding an amino acid (the other three being "terminator signals"). Thus, several different codons encode the same amino acid.

As an analogy, the four DNA bases can be considered the letters of a four-letter alphabet. In this system, the four letters can be arranged in groups of three (codon) to create twenty words (amino acids), and these words in turn can be arranged to create plethora of unique sentences (proteins). Codons which encode the same amino acid can be considered analogous to synonyms.

For example, the following codons: GCA, GCC, GCG and GCT all encode the amino acid Alamine (i.e., they are all "synonyms" for Alanine). "Conservative" amino acid substitutions (whether substituted naturally within the body or artificially in the laboratory) arise when there is a substitution of one chemically related amino acid residue for another without altering or affecting the resulting protein and its properties; for example, in a given protein, an Isoleucine residue substituted at the position of a Leucine residue might be a conservative substitution.

With these technical concepts in mind, the importance of the doctrine of equivalents to the biotechnology industry in assessing the scope of a patented invention is highlighted.

Proteins can comprise hundreds of amino acid residues. Typically, an innovator who discovers a novel and un-

[4] Adenine (A), Thymine (T), Cytosine (C) and Guanine (G).

obvious protein will seek to determine both the DNA sequence encoding the protein and the amino acid sequence of the protein. The invention is typically claimed as a purified and isolated protein and/or a particular amino acid sequence and/or a particular DNA sequence. Thus, for a protein comprising 400 amino acid residues encoded by a DNA molecule comprising 1200 nucleotides, if an infringer generates the protein comprising the exact amino acid sequence and/or the exact DNA sequence as claimed, such an infringer stands accused of literal infringement of the patented invention as defined by the claim.

But, as implied above, with very insubstantial changes, an infringer can readily manipulate the amino acid and/or DNA sequence to generate a functionally identical protein. For example, if a claim specifies a DNA sequence of 1200 nucleotides, by changing just *one* nucleotide out of 1200 (e.g., by changing GC*A* to GC*C*; both encode Alanine), the encoded protein is identical, but the literal language of a claim relating to a specific DNA sequence has been avoided. From an equitable perspective, the invention has nevertheless been violated. In such a situation, the *only* manner in which the innovator can be assured that the invention is not violated is via construing the claim in accordance with the doctrine of equivalents.

If required to protect all of the various sequences in order to secure claims which literally cover all such sequences, the innovator would be required to create thousands of various amino acid sequence and DNA sequence combinations. Both the time and financial resources required for such an endeavor for *one* protein would be enormous. Additionally, the PTO would be required to examine *each* of these equivalent sequences, significantly overloading the agency.[5] Applying for a patent for a

[5] According to the PTO, it is estimated that the computer search time for one hundred separate sequences, each of which not exceeding several hundred DNA bases in length, is about 15 hours and

protein under such a scenario could become an exercise in futility.

In the absence of the doctrine of equivalents, the innovator who has discovered a novel and unobvious protein which is established to be of therapeutic value would be required to direct scarce financial resources away from developing the product and instead into finding all of the various combinations of DNA substitutions and amino acid substitution in order to literally claim all of these equivalents. This perverts the intent of the patent system, i.e., to rapidly encourage and advance innovation. Critical life-saving and life-enhancing therapeutics would be delayed to advance patent form over innovative substance. This cannot be what the Founding Fathers intended when they authorized the Congress to secure for innovators ". . . the exclusive Right to their . . . Discoveries. . ." (*see* U.S. Constitution, Art. 1, Sec. 8, cl. 8).

II. THE DOCTRINE OF EQUIVALENTS SHOULD BE UTILIZED IN PROPERLY DEFINING THE SCOPE AND MEANING OF THE PATENTED INVENTION

BIO strongly disagrees with the view asserted by petitioner in its petition for a writ of certiorari (Pet.) that the doctrine of equivalents is a "second cause of action for infringement" that is "inconsistent not only with the rest of the Patent Act but with well established statutory policy as well." (Pet. at 17, 22) This position, buttressed by an argument that the doctrine of equivalents permits a claim to be grossly distorted to capture unpatented subject matter, is simply incorrect. The court below and this Court's prior opinion in *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950), makes it absolutely clear that the doctrine of equivalents can only

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the examiner time for evaluating the sequence search results in about 65 hours. Thus, it is estimated by the PTO, based upon searching 100,000 separate sequences per year, the estimated cost for computer search time for one hundred sequences is $1,800. *See* 1184 *Official Gazette* 111 (March 26, 1996).

be used to capture insubstantial variations of the claimed invention. As the Court stated in *Graver Tank*:

> "The question which thus emerges is whether the substitution . . . is a change of such substance as to make the doctrine of equivalents inapplicable; or conversely, whether under the circumstances the change was so insubstantial that the trial court's invocation of the doctrine of equivalents was justified"

339 U.S. at 610.

And as recently reiterated by this Court:

> "The claim 'define[s] the scope of the patent grant', and functions to forbid not only exact copies of the invention, but products that go to 'the heart of the invention but avoid the literal language of the claim by making a noncritical change."

Markman, 64 U.S.L.W. at 4264 (citation omitted).

A patent application comprises a specification (35 U.S.C. § 111) and each specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2. Because the claims define the "patented invention," it has been asserted that 35 U.S.C. § 271 must be read to mean that there can only be determination of infringement by prohibited acts involving products or processes which fall four-square within the literal language of the claims. Petitioner has thus asserted that the doctrine of equivalents provides a patentee with an ability to encompass, protect and assert "more than is set forth in the claims." Pet. at 22.

Petitioner seemingly views the doctrine of equivalents as a legal "carnival-mirror" which acts to grossly distort the claimed invention. Nothing could be further from the truth, factually or legally. The doctrine of equivalents is a procedural tool that this Court has recognized and has

endorsed for utilization in defining the scope of protection a patent affords when an accused device or process does not fall within the literal construction of a patent claim. It is an essential doctrine which facilitates appropriate claim construction, as was conducted in this case.[6]

The limitations of words, particularly in emerging technologies such as biotechnology, can often do an injustice to the patented invention. Just as courts may at times go beyond the literal language of a statute for a full appreciation of what the words and boundaries of a statute may be, it is essential that courts have the opportunity to look beyond the literal language of a patent claim to gain a full and complete appreciation of the patented invention. A predecessor court of the Court of Appeals for the Federal Circuit has correctly noted in this context that the imprecision of words is more evident with patent claims that it is with statutes. *Autogiro Co. of America v. United States*, 384 F.2d 391, 398 (Ct. Cl. 1967), *cert. denied*, 434 U.S. 1051 (1978).

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[6] One argument vigorously asserted by petitioner and several *amici* is the need for absolute certainty in determining patent scope and that abolishment of the doctrine of equivalents and restriction of a patent to the literal scope of the claims is a means to that end. This would, of course, limit infringement to situations where the accused device is identical to the claimed invention. It is worth noting that in two other forms of intellectual property protected by Federal law, copyrights (17 U.S.C. §§ 101-1101) and trademarks (15 U.S.C. §§ 1051-1127), that level of certainty is not provided. Thus, copyright infringement does not require an identical copy, but is found where the accused work and the protected work are "substantially similar." *See, for example, Twin Peaks Prod., Inc. v. Publications Int'l Ltd.*, 996 F.2d 1366 (2nd Cir. 1993). The trademark code standard for infringement is met if the accused mark ". . . is likely to cause confusion, mistake or to deceive." *See* 15 U.S.C. § 1114(1)(a). It does not require identity between the protected and accused trademark to meet this test. "Confusing similarity" is enough. *See* McCarthy, *Trademarks and Unfair Competition*, 2nd Ed., Section 21:3, *and cases cited therein*. Thus, copyright and trademark law, just like patent law, also recognize that the subject matter to be protected may not be protected at all if insubstantial variations escape infringement.

The doctrine of equivalents does not provide protection for more than is set forth in the claims. Indeed, the doctrine of equivalents ensures that the patented invention is appropriately protected.

A. The Difference Between The Literal Language Of The Claim And The Accused Device Or Process Must Always Be "Insubstantial"

In understanding the doctrine of equivalents, it is important to recognize that its genesis and development were *not* predicated upon procedures related to the amendment of patent claims. Instead, the doctrine functions as a valuable tool that provides an equitable procedure for both properly construing the meaning and scope of a claim and in ensuring that the patented invention is not violated in the absence of literal infringement. However, just as it is essential to appreciate the role of the doctrine in construing the meaning and scope of a claim, it is equally crucial to recognize that any departure from the literal claim language cannot be more than "insubstantial." As the majority noted below:

> "this court explicitly holds that the application of the doctrine of equivalents rests on the substantiality of the differences between the claimed and accused products or processes, assessed according to an objective standard."

62 F.3d at 1518. This Court provided the same benchmark over 100 years ago, asserting that

> "the substantial equivalent of a thing, in the sense of the patent law, is the same as the thing itself."

Machine Co. v. Murphy, 97 U.S. 120, 125 (1877).

The process for determining whether or not a change is an "insubstantial" change is not subject to a rigid formula. As recognized by this Court, for simple mechanical technology, the determination may often be accomplished and assessed by determining whether the accused devices or processes include substantially the same function, way and result as required by the literal language of a claim

(*see Graver Tank*). As was cogently appreciated and articulated by the court below,

> "As technology becomes more sophisticated and the innovative process more complex, the function-way-result test may not invariably suffice to show the substantiality of the differences."

62 F.3d at 1518. Given that the technology embraced by BIO's members can readily be regarded as "sophisticated," and that the process of innovation in our industry is certainly complex, *amicus* urges the Court to endorse and acknowledge the view articulated by the court below vis-a-vis the limitations of the function-way-result test. In determining the insubstantiality of an accused element, it is not essential that any particular test of analysis be utilized. What is essential is that the analysis objectively focus on whether or not the difference between the accused device or process and the literal language of the claims is "insubstantial."

B. Application Of The Doctrine Of Equivalents Is Limited By The Prosecution History Estoppel Doctrine And The Relevant Prior Art

1. *Prosecution history estoppel doctrine*

The prosecution of a patent application is conducted outside of the public eye. It is a process during which only the PTO and the inventor communicate with each other to the exclusion of any third party (35 U.S.C. § 122; 37 CFR § 1.14), usually in the form of written correspondence, briefs, etc., but sometimes in face-to-face or telephonic meetings (such oral communications are typically summarized in written form by the examiner, and this written summary also becomes a part of the file). However, once a patent is granted and issued by the PTO, all of the correspondence between the PTO and the inventor is available to the public (37 CFR § 1.11). The file which comprises such correspondence can be referred to as the "prosecution history" file.

The prosecution history file allows the public to gain a more complete appreciation and understanding of the

patented invention. For example, it is not unusual during the process of patent prosecution that an inventor will make statements which clarify the meaning of a key term, or to amend a proposed claim in order to overcome, for example, a prior art rejection of that claim. In these situations, the inventor's statements and actions create an estoppel which prevents the inventor from recapturing or redefining during patent litigation that which was abandoned or defined differently during patent prosecution. This type of estoppel has been referred to as the "prosecution history estoppel doctrine."

As has been recognized by this Court, a patentee

> "is not at liberty now to insist upon a construction of his patent which will include what he was expressly required to abandon and disavow as a condition of the grant."

Sutter v. Robinson, 119 U.S. 530, 541 (1886).

While it is correct that the claims of a patent are intended to give notice to the public as to what is considered by the inventor to be the patented invention, from a practical perspective those who review such claims are potential or actual competitors with the inventor and/or assignee of the patented invention. The value and importance of having the prosecution history file open to the public is that competitors in particular can readily determine what may have been abandoned or disavowed by the inventor during prosecution of the patent. That which has been abandoned or disavowed, even if such would otherwise be equivalent to the literal language of the claims, can be freely practiced by any competitor—the prosecution history estoppel doctrine ensures that the doctrine of equivalents is appropriately narrowed as warranted by what transpired during prosecution of the patented invention.

2. *Limitations imposed by the prior art*

The prior art, including information which was available prior to the innovator's discovery (and irrespective of whether the innovator knew of its existence and avail-

ability) also serves to narrow application of the doctrine of equivalents.

A precept of our patent system is that one cannot patent that which is in the prior art, e.g., that which is already freely available to the public. Similarly, a patentee cannot assert that an alleged insubstantial variation is within the scope of the claims if such an insubstantial variation would encompass the prior art. Thus, in construing the scope of the claims under a doctrine of equivalent analysis, the prior art serves as an additional boundary on the scope of the patented invention.

While there are no set procedures for determining how the prior art limits the scope of the patented invention, the Court of Appeals for the Federal Circuit has provided guidance as to one mechanism for conducting such an analysis. This can be accomplished by considering a "hypothetical" patent claim sufficient in scope to literally cover the accused device or process. *Wilson Sporting Goods v. David Geoffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir.), *cert. denied*, 498 U.S. 992 (1990); *c.f. Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570 (Fed. Cir. 1994). Thus, by constructing such a hypothetical claim and by considering the available prior art, a determination can be readily made as to whether such a claim would have been allowed by the PTO—if such a claim would not be allowable over the prior art, and if the accused device or process is encompassed by such a claim, then the accused device or process cannot be viewed as violating the patented invention.

III. THE DOCTRINE OF EQUIVALENTS IS USED TO UNDERSTAND THE SCOPE OF THE PATENTED INVENTION; IT DOES NOT FUNCTION TO CORRECT A DEFECTIVE CLAIM

Under chapter 25 of the Patent Act of 1952 entitled "Amendment and Correction of Patents," one mechanism provided for correcting defects occurring in patents is reissue. 35 U.S.C. § 251; "Reissue of defective patents." The reissue statute provides a way for the patentee to correct defects occurring in an issued patent, including

defects in the claims when such defects make the "wholly or partly inoperative or invalid." 35 U.S.C. § 251.

Petitioner has argued that the doctrine of equivalents is inconsistent with the reissue process. Pet. at 29-30. As petitioner states, "The Federal Circuit's doctrine of equivalents (indeed, any such doctrine) allows 'corrective' enlargement of patent claims without compliance with the conditions and procedures set forth by Congress for reissue." Pet. at 29.

This argument is based on the misapprehension that the doctrine of equivalents serves the purpose of correcting defective claims. In fact, the doctrine of equivalents is *not* intended as a mechanism for correcting or enlarging "broken" claims, nor does it serve this purpose. Instead, the purpose of the doctrine of equivalents is to put claims in their proper perspective as one of the tools for understanding a patented invention and its relationship to an accused product or process in the context of an infringement determination. The doctrine of equivalents thus provides a mechanism for looking beyond the literal terms of a claim (rather than correcting or expanding them) toward a complete understanding of the patented invention. It bears repeating that the doctrine of equivalents only permits a claim to reach an accused device or process which varies insubstantially from that claimed. On the other hand, a reissue proceeding under 35 U.S.C. § 251 permits even glaring mistakes to be corrected and, if done within a two-year from issuance time bar, a patented claim can be expanded to encompass *substantially more* than originally claimed. In short, the reissue process to fix broken patents and the application of the doctrine of equivalents to prevent injustice to the patentee are not in conflict. They are *different* tools to solve *different* problems.

A major difference between reissue and the doctrine of equivalents is that the reissue procedure *can* be used to broaden the scope of a patented invention by ensuring that the claims include subject matter previously excluded from the claims. This occurs when a patentee uses the

reissue procedure to broaden claims and recapture subject matter dedicated to the public in the issued patent (e.g., disclosed in the specification but not claimed) as a result of a defect in the originally issued claims. Because post-issuance broadening of a claim has the potential to prejudice innocent parties who reasonably rely upon the scope of a patented invention conveyed by the original claims, safeguards against this potential for prejudice were included in the 1952 Patent Act. 35 U.S.C. § 251, par. 4 and § 252, par. 2; *see also, Seattle Box Co., Inc. v. Industrial Crating and Packing, Inc.*, 756 F.2d 1574 (Fed. Cir. 1985). These safeguards take the form of a two year time limit on the use of the reissue process to broaden claims and a provision for the grant of intervening rights to those who relied to their detriment upon the original claims.

Because the doctrine of equivalents focusing as it does on *insubstantial* differences does *not* change the scope of a patented invention, the doctrine does not create the same potential for prejudice posed by the reissue procedure. The safeguards imposed on the reissue process to avoid this potential prejudice are, therefore, not required for application of the doctrine of equivalents.

The reissue allows for correction of a defective claim. The doctrine of equivalents does not focus on any perceived defect in the claim language; rather, the doctrine of equivalents focuses on recognizing the scope and meaning of the patented invention. These are fundamentally different concepts.

IV. THE INTENT OF ONE FOUND LIABLE FOR INFRINGEMENT OF A PATENTED INVENTION IS NOT RELEVANT TO THE DETERMINATION OF LIABILITY

Petitioner argues that those who neither had "nor should have had" knowledge of a patent,[7] or have tried

[7] We believe that in a competitive marketplace, those who do *not* take the time to *unilaterally* determine the impact and importance that a competitor's patents may have on their business cannot reasonably expect a judicial body to correct their own competitive malfeasance.

to design around a patent should not be found liable for infringement (Pet. at 29-30). Petitioner urges creation of a "breathing space" rule (Pet. at 30) which would excuse from liability those who did not take the time to see what their competitors have patented or those who, in essence, tried to get as close as possible to the literal language of the claims by reliance upon "insubstantial" variations. We believe the fallacious nature of such a rule is evident. It would rob the doctrine of all vitality because only the most flagrant technology pirates would be liable. All other "infringers" under the doctrine would be excused.

There is but one type of infringement, i.e., infringement of the patented invention under 35 U.S.C. § 271. While intent may be and often is crucial in the assessment of damages after a determination of infringement, intent has no place in the analysis of infringement. Such a conclusion is not only of judicial necessity, but also of practical necessity. The patented invention cannot be subjected to different types of violation which result in different conclusions of liability. There is no such thing as "innocent" infringement and a patentee can legitimately stop a party from making, using, offering for sale, selling or importing a patented invention even if that party did not know of the existence of the patent. *See, Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821 (Fed. Cir. 1991).

CONCLUSION

Sight must not be lost of the fact that the patent system exists to foster innovation. This goal is best met when the patentee is fairly able to reap the rewards of innovative endeavor.

This Court has pointed out that a patent is among the most difficult legal instruments a lawyer is required to

produce. *See, Sperry v. Florida*, 373 U.S. 379, 383 (1963) and *Topliff v. Topliff*, 145 U.S. 156, 171 (1892). The sole purpose of the doctrine of equivalents should be to prevent the draconian result that a patentee, because of the limitations of language, lose all the protection the patent should afford. The doctrine should not require two injustices, i.e., a claim too narrow when literally construed to capture an insubstantial difference and unscrupulous copying, in order to provide relief.

BIO urges this Court to fully support the doctrine of equivalents. Accordingly, this Court should affirm the majority opinion below in its holdings that the standard for determining the scope to which a patent claim is entitled under the doctrine of equivalents is based upon an "insubstantial difference" between the accused device or process, assessed according to an objective standard, and the claimed invention. We further urge this Court to acknowledge that there is no rigid test or formula for determining whether a difference is "substantial." Further, the Court should affirm the holding of the majority below that the intent of one found liable for infringement is not relevant in the determination of such liability.

Respectfully submitted,

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